MAY - 1 2012

Exhibit #1 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K113833

1. Date of Submission: March 2, 2012

2. Sponsor

   Guangdong Biolight Meditech Co., Ltd
   Innovation First Road, Technology Innovation Coast,
   Zhuhai, Guangdong, 519085, China

   Establishment Registration Number: 3007305624

   Contact Person: Mr. Tianbao Li
   Position: Chief Engineer
   Tel: +86-756-3399963
   Fax: +86-756-3399989
   Email: li_tb@blt.com.cn

3. Submission Correspondent
   Ms. Diana Hong
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Vital Signs Monitor
   Proposed Device Model: M900

   Classification: Class II

Product Code: MWI
Regulation Number: 21 CFR 870.2300
Review Panel: Cardiovascular
Subsequent Product Code:

Product Code	Regulation Number	Classification Name	Panel
DXN	870.1130	System, Measurement, Blood-pressure, Non-invasive	Cardiovascular
DQA	870.2700	Oximeter	Anesthesiology
FLL	880.2910	Thermometer, Electronic, Clinical	General Hospital

Intended Use Statement:

The Vital Signs Monitor M900 is used to monitor patient's physiological parameters such as Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), and Temperature (TEMP) continuously. It is intended to be used in health care unit or department, such as out-patient department, emergency department, internal ward, and nursing department.

Proposed Device Name: Vital Signs Monitor
Proposed Device Model: V6

Classification: Class II
Product Code: MWI
Regulation Number: 21 CFR 870.2300
Review Panel: Cardiovascular
Subsequent Product Code:

Product Code	Regulation Number	Classification Name	Panel
DXN	870.1130	System, Measurement, Blood-pressure, Non-invasive	Cardiovascular
DQA	870.2700	Oximeter	Anesthesiology
CCK	868.1400	Analyzer, Gas, Carbon-Dioxide, Gaseous-phase	Anesthesiology
FLL	880.2910	Thermometer, Electronic, Clinical	General Hospital

Intended Use Statement:

The Vital Signs Monitor V6 is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including Oxygen Saturation (SpO2), Carboxyhemoglobin Saturation (SpCO), Methemoglobin Saturation (SpMet), Total Hemoglobin Concentration (SpHb), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO2)

and Temperature (Temp).

It is intended to be used in outpatient departments and emergency treatment rooms of hospitals, community clinics, private clinics and other medical institutions. It is not intended for helicopter transport, hospital ambulance or home use.

5. Predicate Device Identification

510(k) Number: K101445
Product Name: Vital Signs Monitor – VSM 6000 Series
Manufacturer: Welch Allyn, Inc.

510(k) Number: K053174
Product Name: LoFlo C5 CO2 sensor
Manufacturer: Respironics Novametrix, LLC

510(k) Number: K103097
Product Name: Infrared Ear Thermometer
Manufacturer: Radiant Innovation Inc.

510(k) Number: K100046
Product Name: M66 Patient Monitor
Manufacturer: Guangdong Biolight Meditech Co., Ltd

6. Device Description

M900

The proposed device, Vital Signs Monitor M900 is used to monitor patient's physiological parameters such as SpO_2, PR, NIBP and TEMP continuously. It is intended to be used in health care unit or department, such as out-patient department, emergency department, internal ward, and nursing department.

The feature of the M900 is described as following:

Number of Patient for Use

Each monitor can only be used for single patient.

Alarming

There are three kinds of alarming, which are physiological alarming, technical alarming and general alarming.

V6

The proposed device, Vital Signs Monitor V6 is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including Oxygen Saturation (SpO2), Carboxyhemoglobin Saturation (SpCO), Methemoglobin Saturation (SpMet), Total Hemoglobin Concentration (SpHb), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO2) and Temperature (Temp).

The Vital Signs Monitor V6 is intended to be used in outpatient departments and emergency treatment rooms of hospitals, community clinics, private clinics and other medical institutions. It is not intended for helicopter transport, hospital ambulance or home use.

The feature of the V6 is described as following:

Number of Patient for Use

Each monitor can only be used for single patient.

Alarming

There are three kinds of alarming, which are physiological alarming, technical alarming and prompt messages.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1: 1988 +A1:1991+A2:1995, Medical Electrical Equipment – Part 1: General requirements for safety.
- IEC 60601-1-2: 2007, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility – Requirements and tests.
- ASTM E1965-98(reapproved 2009), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

- ISO 10993-5: 1999, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10: 2002, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

8. Clinical Test Conclusion

The clinical test of proposed device Vital Signs Monitor V6 was conducted in People's Hospital in Zhuhai, per ASTM E1965-98(reapproved 2009), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

9. Substantially Equivalent Conclusion

The proposed devices, Vital Signs Monitor, are determined to be Substantially Equivalent (SE) to the predicate device, Vital Signs Monitor – VSM 6000 Series (K101445), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 1 2012

Guangdong Biolight Meditech Co., Ltd.
c/o Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 237-023
Shanghai 200237
CHINA

Re: K113833
Trade/Device Name: Vital Signs Monitors, M900 and V6
Regulatory Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: April 5, 2012
Received: April 12, 2012

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #2 Indications for Use

510(k) Number: K113833
Device Name: Vital Signs Monitor M900

Indications for Use:

The Vital Signs Monitor M900 is used to monitor patient's physiological parameters such as Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), and Temperature (TEMP) continuously. It is intended to be used in health care unit or department, such as out-patient department, emergency department, internal ward, and nursing department.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113833

Exhibit #2 Indications for Use

510(k) Number: K113833
Device Name: Vital Signs Monitor V6

Indications for Use:

The Vital Signs Monitor V6 is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including Oxygen Saturation (SpO2), Carboxyhemoglobin Saturation (SpCO), Methemoglobin Saturation (SpMet), Total Hemoglobin Concentration (SpHb), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO2) and Temperature (Temp).

It is intended to be used in outpatient departments and emergency treatment rooms of hospitals, community clinics, private clinics and other medical institutions. It is not intended for helicopter transport, hospital ambulance or home use.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Cardiovascular Devices

510(k) Number K113833